AMENDMENTS TO THE CLAIMS

This listing of claims replaces all prior versions and listings of the claims.

Deletions are indicated by double brackets and/or strikethrough, and additions are indicated by underlining.

1-36. (Cancelled)

37. (Currently Amended) A method of treating or managing cancer comprising:

administering to a patient a pharmaceutical composition ~~comprising~~ with an effective amount of a therapeutic agent related from the group consisting of: a) heat killed whole cell *Mycobacterium w* and b) ~~or sonicated *Mycobeterium* w, or a solvent extract of *Mycobacterium w*, wherein the solvent is selected from chloroform, ethanal, methanol, acetone, phenol, isopropyl alcohol, isopropyl alcohol, acetic acid, urea and hexane~~ an enzymatic extraction of *Mycobacterium w*, wherein the enzyme is selected from the group consisting of liticase and pronase.

38. (Previously Presented) The method of claim 37, wherein the method is for decreasing the burden of cancer tissue.

39. (Previously Presented) The method of claim 37, wherein the method is for increasing the efficacy of radiotherapy or chemotherapy in the treatment of cancer.

40. (Previously Presented) The method of claim 37, wherein the method is for reducing the side effect of radiotherapy or chemotherapy.

41. (Previously Presented) The method of claim 40, wherein the side effects are hematological side effects.

42. (Previously Presented) The method of claim 40, wherein side effect are reduced to avoid interruption of chemotherapy.

43. (Previously Presented) The method of claim 40, wherein the side effects are leucopenia, thrombocytopenia, anaemia, nausea, vomiting or mucositis.

44. (Cancelled) ~~The method of claim 37, wherein the *Mycobacterium w* is dead *Mycobacterium w*.~~

45. (Cancelled) ~~The method of claim 44, wherein the *Mycobacterium w* has been killed by a physical method.~~

46. (Cancelled) ~~The method of claim 45, wherein the physical method is the application of heat.~~

47. (Currently Amended) The method of claim [[46]]37, wherein the heat for killing is applied by means of autoclaving.

48-51. (Cancelled)

52. (Previously Presented) The method of claim 37, wherein the pharmaceutical composition further comprises one or more adjuvants.

53. (Previously Presented) The method of claim 52, wherein the pharmaceutical composition further comprises a surfactant.

54. (Previously Presented) The method of claim 53, wherein the surfactant is polyoxyethylene (20) sorbitan monooleate.

55. (Previously Presented) The method of claim 53, wherein the pharmaceutical composition comprises a surfactant in an amount up to 0.4% by weight/volume of the pharmaceutical composition.

56. (Previously Presented) The method of claim 53, wherein the pharmaceutical composition comprises a surfactant in an amount up to 0.1% by weight/volume of the pharmaceutical composition.

57. (Previously Presented) The method of claim 37, wherein the *Mycobacterium w* is urease negative, dose not hydrolyze polyoxyethylene (20) sorbitan monooleate, does not produce niacin, and provides a strong positive response to nitrate reduction tests.

58. (Previously Presented) The method of claim 37, wherein the pharmaceutical composition is administered alone or in combination with other modes of therapy selected from radiotherapy and chemotherapy.

59. (Previously Presented) The method of claim 37, wherein the pharmaceutical composition is administered by parenteral route.

60. (Previously Presented) The method of claim 37, wherein the pharmaceutical composition is administered by intramuscular, subcutaneous or intradermal route.

61. (Previously Presented) The method of claim 37, wherein the pharmaceutical composition is in a unit dosage form comprising at least 10^5 *Mycobacterium w*.

62. (Previously Presented) The method of claim 37, wherein the pharmaceutical composition is in a unit dosage form comprising at least 10^7 *Mycobacterium w*.

63. (Previously Presented) The method of claim 37, wherein the pharmaceutical composition is in a unit dosage form comprising from 10^8 to 10^{10} *Mycobacterium w*.

64. (Previously Presented) The method of claim 37, wherein the pharmaceutical composition further comprises a preservative.

65. (Previously Presented) The method of claim 37, wherein the cancer is a primary or a secondary metastatic lesion.

66. (Currently Amended) A method of improving the quality of life in a patient suffering from cancer comprising:

administering to a patient a pharmaceutical composition ~~comprising~~ with an effective amount of a therapeutic agent selected from the group consisting of: a) heat killed whole cell *Mycobacterium w* ~~or sonicated *Mycobeterium* w, or a solvent extract of *Mycobacterium w*,~~

~~wherein the solvent is selected from chloroform, ethanal, methanol, acetone, phenol, isopropyl alcohol, isopropyl alcohol, acetic acid, urea and hexane or~~ and b) an enzymatic extraction of *Mycobacterium w*, wherein the enzyme is selected from the group consisting of liticase and pronase.

67. (Previously Presented) The method of claim 66, wherein the improvement in quality of life is obtained in the absence of other modes of treatment.

68. (Previously Presented) The method of claim 66, wherein the improvement in quality of life is obtained with addition of other modes of treatment selected from radiotherapy and chemotherapy.

69. (Currently Amended) A method of amelioration of symptoms associated with cancer comprising:

administering to a patient a pharmaceutical composition ~~comprising~~ with an effective amount of therapeutic agent selected from the group consisting of a) heat killed whole cell *Mycobacterium w* ~~or sonicated *Mycobeterium* w, or a solvent extract of *Mycobacterium w*, wherein the solvent is selected from chloroform, ethanal, methanol, acetone, phenol, isopropyl alcohol, isopropyl alcohol, acetic acid, urea and hexane or~~ and b) an enzymatic extraction of *Mycobacterium w*, wherein the enzyme is selected from the group consisting of liticase and pronase, wherein the symptoms associated with cancer are selected from the group consisting of pain, abnormal hemoglobin, cough, breathlessness, dysphagia, neutropenia and irregular sleep.

70. (Currently Amended) The method of treating cancer according to claim 37, wherein the pharmaceutical composition is administered is administered [[by]] intradermally.

71. (Previously Presented) The method of treating cancer according to claim 37, wherein the cancer is superficial bladder cancer and the composition is administered intradermally over the deltoid region.

72. (Previously Presented) The method of treating cancer according to claim 37, wherein the cancer is muscle invasive bladder cancer and the composition in administered intradermally over the deltoid region.